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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/010,607 | 12/10/2001 | Bruce George Sharpe | | 6656 |

7590 03/26/2004

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| EXAMINER |
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HAN, MARK K

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| ART UNIT | PAPER NUMBER |
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3763

DATE MAILED: 03/26/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,607

Applicant(s)

SHARPE, BRUCE GEORGE

Examiner

Mark K Han

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10 is/are allowed.
- 6) ☒ Claim(s) 11 and 13-19 is/are rejected.
- 7) ☒ Claim(s) 1, 10 and 12 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Specification

1. The spacing of the lines of the specification is such as to make reading and entry of amendments difficult. New application papers with lines double spaced on good quality paper are required.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: spring assembly (reference numeral 11-15, p. 4, line 12); reference numeral F12 (p. 4, line 14); spring activating clip 10 (p. 4, par. 3, lines 6, 8 and p. 5, line 1). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: reference numeral 10abc (Fig. 5). A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "6" and "9" have both been used to designate sealing member (Fig. 5). A proposed drawing correction or corrected drawings are required in reply to the Office action to

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avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

5. The claims are objected to because the lines are crowded too closely together, making reading and entry of amendments difficult. Substitute claims with lines one and one-half or double spaced on good quality paper are required. See 37 CFR 1.52(b).

6. Claims 1 and 10 are objected to because of the following informalities: Claims 1 and 10 recite the limitation "the springs" in line 13 of both claims. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,046,508 to Weissler.

Weissler shows a syringe having a cylindrical body element 70, plunger rod (not shown, but inherently part of the device), needle assembly 72, needle holding member 114, retaining member 130 and activating member 122. See Figures 2-5.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weissler.

In reference to claims 13-17, Weissler discloses the claimed invention as shown above. Weissler does not disclose expressly twin conical helical springs between a pair of spring retaining cups with a spring separation member. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to replace the spring of Weissler with the claimed spring assembly because Applicant has not disclosed that the claimed spring assembly provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a single spring because both assemblies provide a means of biasing the needle assembly. Therefore, it would have been an obvious matter of design choice to modify Weissler to obtain the invention as specified in claims 13-17.

In reference to claims 18 and 19, Weissler shows a slide member 128 but does not show a plurality of activation members. It would have been obvious to one of ordinary skill in the art to modify the invention of Weissler by duplicating the activation member because it has been held that duplication of parts have no patentable significance. See *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Allowable Subject Matter

9. Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 1-10 are allowed.

11. The following is a statement of reasons for the indication of allowable subject matter:

The subject matter of the independent claims could either not be found or was not suggested in the prior art of record. The subject matter not found was the retraction mechanism having springs between the needle holding member and the axial end of the cylindrical body element, at least one retaining member engaging the needle holding member and retaining the needle holding member, at least one activating member within the needle holding member that responds to positive fluid pressure within the fluid chamber to release the retaining member where the needle is automatically deployed into the injecting position by depressing the plunger prior to drawing fluid and is automatically retracted within the body element at the end of the injection stroke in combination with the other elements (or steps) in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K Han whose telephone number is 703-308-4543. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mkh.

Mark Han
Patent Examiner
Art Unit 3763

mkh
March 16, 2004

Brian L. Casler
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TECHNOLOGY CENTER 3700